

Positron Emission Tomography Standard Advisory Committee (PETSAC)  
Status of the Charge – Working Document

Charge	Current Standards	Status of Recommendation
<p>1. Second unit volume requirement related to expansion.</p>	<p>Section 2(1)(o) "Expand a fixed PET scanner service" means increasing the number of fixed PET scanners at the same geographic location of an existing fixed PET scanner service.</p> <p>(p) "Expand a mobile PET scanner service" means the addition of a mobile PET scanner that will be operated by a central service coordinator in the same planning area in which the CSC is approved primarily to operate one or more mobile PET scanners as of the date an application is submitted to the Department.</p> <p>Section 5 An applicant proposing to increase the number of PET scanners (second, third, etc.), whether fixed or mobile, unless otherwise specified, in addition to a PET scanner previously approved for the same applicant, shall demonstrate the following:</p> <p>(a) All of the applicant's PET scanners, both fixed and mobile, at the same geographic location as the proposed additional PET unit, have performed an average of at least 6,000 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.</p> <p>(b) In the case of a fixed PET scanner service, the additional PET scanner shall be located at the same geographic location as the applicant's existing fixed PET scanner/service. If the scanner will not be located at the same geographic location, the applicant must meet the requirements to initiate or expand a PET scanner service <u>at the proposed location/site</u>, in accordance with Section 4 or Section 5, respectively.</p>	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>• Definitions in Section 2 for metro, micro, and rural areas</li> <li>• Changes made to Section 5 in adding metro, micro, rural language and corresponding expansion numbers of 5500, 5000, and 4500</li> <li>• Problems with determining whether both fixed and mobile existing at site must meet numbers; specifically whether mobile existing must meet at specific site or network wide</li> </ul> <p>Final Recommendation:</p>
<p>2. Requirements for conversion of mobile to fixed units.</p>	<p>No applicable sections.</p>	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>• Mobile to fixed conversion: Section 4(4); need to determine whether volume is from host site or network wide</li> <li>• Fixed to mobile conversion: Section 5(3)</li> </ul> <p>Final Recommendation:</p>

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3.	85/15 requirement for mobile PET scanner services as identified under Sections 15, 17, and 18.	<p>Section 12(1)(h) At least 85 percent of the PET scans provided by the mobile PET scanner/service, annually, must be provided within the single planning area from which 85 percent of the diagnosis specific new cancer case, diagnostic cardiac catheterization, and/or intractable epilepsy data, as referenced in sections 15, 17, and 18, as applicable, was obtained for approval of the mobile PET scanner network.</p> <p>Section 15(1)(d) For mobile PET scanner services, at least 85 percent of the diagnosis specific new cancer case data is from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) will be provided.</p> <p>Section 17(1)(c) For mobile PET scanner services, at least 85 percent of the diagnostic cardiac catheterization data is from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) will be provided.</p> <p>Section 18(1)(c) For mobile PET scanner services, at least 85 percent of the intractable epilepsy data is from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) will be provided.</p>	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Deleted 85/15 language throughout</li> <li>Added 3 year limit of cancer data to Section 15, 17, and 18</li> </ul>
			Final Recommendation:
4.	Rural exceptions, if necessary.	No applicable sections.	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Metro, micro, and rural definitions added</li> <li>Rural expansion number added to Section 5 pursuant to Charge 1 directive</li> <li>No other rural language suggestions made by PETSAC to date</li> </ul>
			Final Recommendation:
5.	Positron Emission Mammography (PEM) requirements and other new technology.	No applicable sections.	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>No language offered by PETSAC to date</li> </ul>
			Final Recommendation:

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6.	Minimum volume requirements for mobile host sites.	No applicable sections.	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Section 4(3); Section 11(1)(c)(viii);</li> <li>Possible language changes in Section 4 (initiation) and Section 11 and Section 12 (project delivery requirements)</li> </ul> <p>Final Recommendation:</p>
7.	Requirements for relocation.	No applicable sections.	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Added language submitted by Spectrum to Sections 2, 5, 6, 7, and Section X</li> <li>Need to determine where Section X is to be integrated or inserted</li> </ul> <p>Final Recommendation:</p>
8.	Duration of commitment of data associated to a PET service.	<p>Section 15(1)(b) Each entity contributing diagnosis specific new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnosis specific cancer cases being committed to the application and that states no current or future diagnosis specific new cancer case data will be used in support of any other application for a PET unit for the duration of the PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.</p> <p>Section 15(1)(e) No entity contributing diagnosis specific new cancer case data is listed on the "Department Inventory of Pet Scanners," nor does it have a pending application to initiate PET scanning service.</p> <p>(2) No entity currently operating or approved to operate a unit listed on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases to support any PET service/scanner.</p> <p>(3) No entity that has contributed any diagnosis specific cancer case data to another PET application for which the approved PET scanner service still is operational shall commit cancer case data to any other application.</p>	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Added 3 year limit of cancer data to Section 15, 17, and 18; discuss possible 4 or 5 years based upon CON approval date vs. 3 years based upon initiation of first scan by unit</li> </ul> <p>Final Recommendation:</p>

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9.	Requirements for replacement.	Section 2(1) (pp) "Replace a PET scanner" means an equipment change, other than an upgrade, involving either a PET scanner, an accelerator if located on site, or other equipment related to the operation of the PET scanner service proposed by an applicant that results in that applicant operating the same number of PET scanners before and after project completion. Section 6(1) – (3).	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Changes to Section 6, including minimum volume requirements</li> </ul> <p>Final Recommendation:</p>
10.	Requirements for acquisition.	<p>Section 2(1)(b) "Acquisition of an existing PET scanner service" means obtaining possession or control of an existing PET service/unit(s) by contract, ownership, lease, or other comparable arrangement.</p> <p>Section 7. An applicant proposing to acquire an existing PET scanner service, whether fixed or mobile, shall demonstrate that it meets all of the following:</p> <p>(a) The project is limited solely to the acquisition of an existing PET scanner/service and does not involve a change in the geographic location of the scanner(s).</p> <p>(b) The project will not change the number of PET scanners listed on the Department Inventory of PET Scanners at the geographic location of the PET scanner service being acquired, unless the applicant demonstrates that the project is in compliance with the requirements of Section 3, 4, or 5, as applicable.</p> <p>(c) The project will not result in the replacement of the PET scanner(s) at the PET scanner service to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.</p> <p>(d) All PET scanners to be acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department.</p> <p>(e) The applicant agrees to operate the PET scanner service in accordance with all applicable project delivery requirements set forth in Section 11 of these standards.</p>	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>Changes to Section 7; need to determine minimum volume that acquired scanners should be performing</li> <li>Discuss "one-time volume-less" acquisition similar to CT Standards</li> <li>Section X impact</li> </ul> <p>Final Recommendation:</p>
11.	Cancer Registry Data (New Charge Point)	No applicable sections.	<p>Discussion Points:</p> <ul style="list-style-type: none"> <li>No language offer by PETSAC to date; determine impact of changes on data</li> <li>Discuss 3 year rule</li> </ul> <p>Final Recommendation:</p>